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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 71

[Docket No. APHIS-2007-0039]

RIN 0579-AC61

Recordkeeping for Approved Livestock Facilities and Slaughtering and Rendering Establishments

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the interstate movement of livestock to require approved livestock facilities and listed slaughtering and rendering establishments to maintain certain records for 5 years. Currently, approved livestock facilities are required to retain certain records for 2 years, and there are no record retention provisions that apply to listed slaughtering and rendering establishments. Requiring the retention of certain records for 5 years will allow us to trace the prior movements of diseased livestock further into the past than is currently possible, thus providing the opportunity to locate potentially infected or exposed livestock that might otherwise remain unidentified. We are also requiring the operators of slaughtering and rendering establishments to sign listing agreements to document their agreement to comply with the requirements of the regulations for listed slaughtering and rendering establishments. Such agreements are currently required for approved livestock

facilities, but not for slaughtering and rendering facilities. This change will eliminate that inconsistency.

EFFECTIVE DATE: [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Debra C. Cox, Senior Staff Veterinarian, National Surveillance Unit, Centers for Epidemiology and Animal Health, VS, APHIS, 4700 River Road Unit 200, Riverdale, MD 20737; 301-851-3504.

#### SUPPLEMENTARY INFORMATION:

##### Background

The regulations in subchapter C of chapter I, title 9, of the Code of Federal Regulations contain provisions designed to prevent the dissemination of livestock or poultry diseases in the United States and to facilitate the control and eradication of such diseases. The regulations in 9 CFR part 71 (referred to below as the regulations) include general prohibitions on the interstate movement of animals that could spread livestock or poultry diseases.

The regulations in § 71.20 contain provisions under which livestock facilities may acquire and retain status as an approved facility. To obtain approval, facilities must enter into an agreement with the Animal and Plant Health Inspection Service (APHIS) in which they agree to follow certain procedures when handling livestock entering the facility. Part of this agreement states that documents such as weight tickets, sales slips, and records of origin, identification, and destination that relate to livestock that are in, or that have been in, the facility shall be maintained by the facility for a period of 2 years. Such records would be critical in the event that APHIS or State animal health officials needed to conduct a disease traceback investigation.

On July 7, 2008, we published in the Federal Register a proposed rule<sup>1</sup> (73 FR 38343-38346, Docket No. APHIS-2007-0039) to amend the regulations to require approved livestock facilities and listed slaughtering and rendering establishments to maintain certain records for 5 years. We also proposed to require the operators of slaughtering and rendering establishments to sign listing agreements to document their agreement to comply with the requirements of the regulations for listed slaughtering and rendering establishments.

We solicited comments for 60 days ending September 5, 2008. We received four comments by that date. They were from two private citizens (one of whom submitted two comments) and a rendering industry association. Two of the commenters expressed concerns about farm animal welfare and general dissatisfaction with the United States Department of Agriculture, but did not address the specific provisions of the proposed rule. The third commenter raised a number of specific concerns regarding the proposed rule. They are discussed below.

The commenter stated that we were incorrect to say that there are no recordkeeping requirements for rendering establishments, noting that the Food and Drug Administration (FDA) requires rendering establishments to keep records. The commenter questioned why rendering establishments should be subject to more stringent recordkeeping requirements by APHIS than by FDA and stated that the agencies should better coordinate their recordkeeping requirements.

The commenter is correct that the FDA has recordkeeping requirements in 21 CFR part 589 that apply to rendering establishments; however, those regulations require records to be kept for 1 year only. In our proposed rule, we noted that there are currently no APHIS requirements for recordkeeping by rendering establishments. APHIS attempts to coordinate its

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<sup>1</sup> To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0039>.

recordkeeping requirements with other agencies whenever possible, and we do not expect rendering establishments to keep different categories of records from what they already keep under FDA requirements. However, some animal diseases have incubation periods of several years, and an animal disease investigation may require tracing animals that were exposed to an infected animal several years before the outbreak occurred. If exposed animals have been slaughtered or died and been sent to a rendering establishment, we need to be able to confirm that they reached these terminal points. For this reason, we need the records to be kept for longer than 1 year. We are making no changes to the final rule in response to this comment.

The same commenter stated that, because of increased costs associated with the 2008 FDA ruminant feed ban rule, there may be an increased number of carcasses disposed of illegally. The commenter asked why APHIS has not addressed the issue of carcass disposal.

In its final rule prohibiting the use of certain cattle origin materials in the food or feed of all animals, published in the Federal Register on April 25, 2008 (73 FR 22720-22758, Docket No. 2002N-0273), FDA responded to comments that expressed the same concern regarding the impact the FDA rule could have on the availability and cost of disposal of cattle material prohibited in animal feed and dead stock cattle. In its response, FDA acknowledged that carcass disposal problems exist in certain States or regions and that developing and implementing adequate solutions to these problems is challenging. On April 24, 2009, FDA published a document confirming the effective date of the April 2008 final rule (74 FR 18626-18628, Docket No. FDA-2002-N-0031) and announced that it would delay compliance with the provisions of the April 2008 final rule until October 26, 2009, stating that a delay in the compliance date would allow the significant number of stakeholders affected by the April 2008 final rule more time to comply with the new regulations or adjust to the loss of rendering service. In that notice,

FDA also acknowledged that it might be particularly challenging to address such disposal problems by the compliance date. FDA issued a revision of the Small Entities Compliance Guide for Renderers on May 6, 2009, and has stated its intent to engage in further outreach to the rendering industry, pertinent State agencies, and others affected by the rule. APHIS has been working and will continue to work with FDA to address any animal disease issues associated with implementation of the feed ban rule, and will revisit the issue of carcass disposal if necessary. We are making no changes to the rule in response to this comment.

The commenter stated that APHIS's animal disease traceability program does not address animal identification beyond death unless the animal is slaughtered in a federally inspected slaughter facility. The commenter expressed concern that without stronger identification requirements for animals and carcasses, additional recordkeeping requirements for renderers will have no benefit for animal health.

The commenter is correct that APHIS' animal disease traceability program focuses on the identification of live animals rather than of carcasses. We did not propose to require renderers to keep traceability information for carcasses they collect, or to establish new categories of records, but only to keep the records they do have for a longer period of time. We acknowledge that there may be an animal disease risk from products produced by rendering an animal that has died of disease; however, primary authority for regulating rendered products falls to the Food Safety and Inspection Service and FDA. APHIS has worked and will continue to work with these agencies to ensure that any animal disease issues associated with these products are addressed. We are making no changes in response to this comment, however.

It is necessary for us to make a change in this rule so that its provisions are consistent with those of our final rule on animal disease traceability (see 78 FR 2040-2075, Docket No.

APHIS-2009-0091). Specifically, in that final rule we acknowledge, in responding to comments, that the lifespans of poultry and swine are relatively short compared with those of other species of livestock, and that records for those animals do not, therefore, need to be kept as long as records for other animals. Hence, in that final rule, we provided for the retention of records for poultry and swine to 2 years rather than 5. To be consistent, this final rule keeps the recordkeeping period for poultry and swine at 2 years. Records for cattle, bison, sheep, goats, cervids, and equines will still be required to be kept for 5 years.

In addition, we are making a change to § 71.20(a)(8) to add a reference to 9 CFR part 86 to the list of regulations under which livestock must be identified at the time of, or prior to, entry into a livestock facility. This change should have been included in the animal disease traceability final rule but was inadvertently omitted.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also examines the potential economic

effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

This rule amends the regulations regarding the interstate movement of livestock to require approved livestock facilities and listed slaughtering and rendering establishments to maintain certain records for 5 years. Currently, approved livestock facilities are required to retain certain records for 2 years. No record retention provisions currently apply to listed slaughtering and rendering establishments.

For some livestock diseases, the incubation period (the time from when an animal becomes infected until the disease is evident) can last for years before clinical or behavioral signs become apparent. A prime example is bovine tuberculosis, a contagious disease of both animals and humans caused by specific types of bacteria that are part of the Mycobacterium group. The incubation period for bovine tuberculosis can range from months to years. By requiring record retention for 5 years, the rule will benefit APHIS and State animal health authorities, the operators of livestock, slaughtering, and rendering facilities, and livestock producers, generally, in the event that a traceback is required to locate the source herd of an animal discovered to have a disease such as bovine tuberculosis.

The rule is not expected to result in significant costs for the affected entities. An analysis of similar recordkeeping costs expected to be incurred in connection with a May 2012 Food Safety and Inspection Service rulemaking (75 FR 14361-14368, Docket No. FSIS-2008-0025) found the costs to be minimal. For approved livestock facilities that are already required to

retain records for 2 years, and rendering facilities that are currently maintaining relevant records per FDA's requirements, the costs will be smaller still.

The alternative to the rule would be to leave the regulations unchanged. In doing so, possible reductions in losses associated with animal diseases that have long incubation periods would not be realized. The rule is preferred to the current regulations, given the relatively minor recordkeeping costs that would be incurred to achieve improved traceback capabilities.

The benefits of the rule will justify its costs. There were no comments received on the economic analysis prepared for the proposed rule, nor were other significant economic issues raised. While the majority of approved livestock facilities, slaughtering establishments, and rendering establishments are small entities, costs incurred because of the rule are also expected to be small.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.



## Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

## Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579-0342, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the Federal Register providing notice of what action we plan to take.

## E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

## List of Subjects in 9 CFR Part 71

Animal diseases, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we are amending 9 CFR part 71 as follows:

## PART 71--GENERAL PROVISIONS

1. The authority citation for part 71 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

2. Section 71.20 is amended as follows:

a. By revising paragraph (a)(7) to read set forth below.

b. In paragraph (a)(8), by removing the words “and 85” and adding the words “85, and 86” in their place.

c. In the OMB citation at the end of the section, by removing the words “number 0579-0258” and adding the words “numbers 0579-0258 and 0579-0342” in their place.

§ 71.20 Approval of livestock facilities.

(a) \* \* \*

(7) Documents such as weight tickets, sales slips, and records of origin, identification, and destination that related to livestock that are in, or that have been in, the facility shall be maintained by the facility. For poultry and swine, such documents must be kept for at least 2 years, and for cattle and bison, sheep and goats, cervids, and equines, for at least 5 years. APHIS representatives and State representatives shall be permitted to review and copy those documents during normal business hours.

\* \* \* \* \*

3. Section 71.21 is amended as follows:

a. By redesignating paragraphs (a)(1), (a)(2), and (a)(3) as paragraphs (a)(2), (a)(3), and (a)(4), respectively, and by adding a new paragraph (a)(1) to read as set forth below.

b. By adding a new paragraph (a)(5) to read as set forth below.

c. In the OMB citation at the end of the section, by removing the words “number 0579-0212” and adding the words “numbers 0579-0212 and 0579-0342” in their place.

§ 71.21 Tissue and blood testing at slaughter.

(a) \* \* \*

(1) The owner or operator of the establishment must agree, in writing, to meet the requirements for a listed facility under this section by signing a listing agreement.

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(5) The management of the slaughtering or rendering establishment agrees that weight tickets, sales slips, and records of origin, identification, and destination that relate to livestock that are in, or have been in, the establishment will be maintained by the establishment. For poultry and swine, such documents must be kept for at least 2 years, and for cattle and bison, sheep and goats, cervids, and equines, for at least 5 years. APHIS, APHIS contractors, and State animal health representatives will be permitted to review and copy or scan these documents during normal business hours.

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Done in Washington, DC, this 2<sup>nd</sup> day of May 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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